

**Notice of Allowability**

Application No.

10/810,358

Examiner

SHULAMITH H. SHAFER

Applicant(s)

CHEN ET AL.

Art Unit

1647

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/29/10.
2. ☒ The allowed claim(s) is/are 1,3,5-8,11-21,46-49, now renumbered 1-20.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application                      |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date <u>10/29/04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                   | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|  | 9. <input checked="" type="checkbox"/> Other <u>413B, 1/12/11</u> .                    |

### **Detailed Action**

#### ***Status of Application, Amendments, And/Or Claims:***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 November 2010 has been entered.

Claims 1, 7, 46 and 49 have been amended and the amendment made of record.

Claims 1, 3, 5-8, 11-21 and 24-49 are pending in the instant application. Claims 13-15 and 24-45 stand withdrawn as being drawn to a non-elected invention.

Claims 1, 3, 5-8, 11, 12, 16-21 and 46-49 are under consideration.

### **Withdrawn Objections/Rejections**

The objection to Claim 48 is withdrawn in light of Applicants amendment to the claim.

Applicants' amendment to Claims 1 and 46 overcomes the following rejections over the prior art:

The rejection of Claims 1, 3, 5, 16, 17, 19, 20 and 46 under 35 U.S.C. 103(a) as being unpatentable over Togawa et al. in view of Hart et al.

The rejection of Claims 18 and 21 under 35 U.S.C. 103(a) as being unpatentable over Togawa et al. and Hart et al. as applied to claims 1, 17 and 20 in view of Vignali et al.

The rejection of Claims 6-8 and 47-49 under 35 U.S.C. 103(a) as being unpatentable over Togawa et al. and Hart et al as applied to claim 1 and claim 46 in view of Blumberg et al. (1999. Current Opinion in Immunology 11:648-656)

The rejection of Claims 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over Togawa et al. and Hart et al. as applied to claim 1 in view of Bing et al.

### Rejoinder of Claims

Claim 1 is allowable. Pursuant to the procedures set forth in MPEP § 806.04, claims 13-15, directed to non-elected species, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.141.

Because a claimed species previously withdrawn from consideration has been rejoined, **the requirement for species election (c) in Office Action of 16 May 2006 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined species, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney H. W. Wherley on 12 January 2011.

Claims 24-45 are canceled.

### **Conclusion:**

Claims 1, 3, 5-8, 11-21 and 46-49 are allowed.

The following is an examiner's statement of reasons for allowance:

Applicants' have amended independent claims 1 and 46 to recite "a method of determining the efficacy of a probiotic as a treatment of **irritable bowel syndrome** in mammals *in vivo*..." (Emphasis added by the Examiner). The art teaches (See, for example Grundmann et al. 2010. J. Gastroenterology and Hepatology 25:691-699). "IBS is characterized as a functional disorder of the GI tract associated with abdominal pain and altered bowel activity but lacking any pathological organic changes. This distinguishes it from inflammatory bowel disease (IBD), which presents with increased phagocyte-specific protein in the feces, in that IBS does not cause inflammation as can be assessed with a differential blood test and fecal markers, observation of ulcers, or other organic damage to the GI tract.....[T]he absence of organic pathophysiological changes distinguishes IBS from many other GI disorders such as Crohn's disease, ....." (page 692, 2<sup>nd</sup> column, 2<sup>nd</sup> full paragraph). The primary reference cited in rejections of record, Togawa et al. does not anticipate nor render obvious the claims of the instant invention as it is directed to methods of evaluating treatment in an animal model of Crohn's disease.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHULAMITH H. SHAFER whose telephone number is (571)272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shulamith H. Shafer/  
Primary Examiner, Art Unit 1647